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EXAMINER	
LOPEZ, AMADEUS SEBASTIAN	
ART UNIT	PAPER NUMBER
3771	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/816,014	SCHOLLER ET AL.	
	Examiner	Art Unit	
	Amadeus S. Lopez	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 11/24/2006 have been fully considered but they are not persuasive. The applicant makes the argument that "independent claim 1 recites that when the analyzing yields a result indicating a functional disturbance or an increase risk device failure... and Froehlich's apparatus includes a controller 17 that places a blower 12 in a standby mode when the controller 17 senses an unimpeded air flow (e.g. if the mask is removed from the patient or a gross leak occurs). Froehlich goes on to explain that if desired, an alarm may be sounded to alert the patient that the apparatus has been placed in the standby mode. In other words, Froehlich's alarm is indicative of the operational mode of the apparatus." As stated, Froehlich's CPAP device automatically enters the standby mode if the mask is removed from the patient or a gross leak occurs, which are both indicative of a "functional disturbance or an increased risk of device failure." The placement of the ventilator into a standby mode is directly related to a functional disturbance or an increased risk of device failure. Therefore one of ordinary skill in the art would be able to comprehend that when the device alarms, this is not only indicative of the operational mode but also of a functional disturbance of the device. The argument that the alarm is simply indicative of an operational mode is not persuasive because it is obvious that the alarm correlates to a functional disturbance of the device and that is the reason the device is placed into the standby mode and contains an alarm to notify the user that they must fix the functional disturbance.

Specification

The disclosure is objected to because of the following informalities:

The specification lacks the proper sub-headings including: Background of the Invention, Summary of the Invention, Description of the Drawings, etc.

Appropriate correction is required.

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject

matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation.

There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruenke et al. ('373) in view of Behbehani et al. ('952) and Froehlich et al. ('146).

As to claim 1, Gruenke et al. disclose a procedure for the control of a respirator device, in which one can set at least two different levels (col.6, lines 30-34) for a breathable gas supply, comprising: capturing at least three parameters by measurement technique (col.20, lines 26-53); evaluating the at least three parameters (col.20, line 62-col.22, line 36); and wherein the respirator device is controlled in an adaptive manner

such that time-wise evolution of the at least three parameters maintain, at most, a predefined maximum difference from the typical evolution patters, and wherein the at least three parameters include respiratory pressure (1806), respiratory flow (1802) and respiratory impedance (col.20, lines 47-53); and wherein a CPAP respirator treatment is carried out (col.6, lines 30-34 and col.12, lines 41-42).

To the extent, if any that Gruenke et al. lack the step of capturing the parameter of respiratory impedance (inasmuch as Gruenke et al. expressly disclose the derivation of respiratory admittance which is the inverse of respiratory impedance), resort is had to Behbehani et al., in a CPAP device, which teach the capturing the parameter of respiratory impedance for the purpose of determining an estimate of the degree of obstruction of the airway of a patient's respiratory system (col.2, lines 10-20) so that a proper amount of CPAP pressure may be calculated and applied to a patient's airway in order to maintain airway patency.

It would have been obvious to modify the method of respirator control of Gruenke et al. to capture the parameter of respiratory impedance by any well known method including a forced oscillation technique because it would have provided an estimate of the degree of obstruction of the airway of a patient's respiratory system so that a proper amount of CPAP pressure may be calculated and applied to a patient's airway in order to maintain airway patency as taught by Behbehani et al..

The difference between Gruenke et al. as modified by Behbehani et al. and claim 1 is the step of based on a pattern recognition, analyzing at least one characteristic of the

respirator device selected from the group consisting of defect, reduced performance, leak in the region of the apparatus or in the region of a hose connection.

Froehlich et al. (col.8, lines 41-59) in a CPAP respirator, teach based on a pattern recognition, analyzing at least one characteristic of the respirator device selected from the group consisting of defect, reduced performance, leak in the region of the apparatus or in the region of a hose connection. More specifically, Froehlich et al. (col.8, lines 41-59) teach the steps of recognizing and analyzing a pattern of pressure and flow of breathable gas that is consistent with a leak or disconnection of the supply hose and subsequently placing the ventilator in a standby mode for the purpose of preventing the wasting of breathable gas. Further it is disclosed by Froehlich that when analyzing yields a result indicating a functional disturbance or an increased risk device of device failure, generating a signal indicative of the functional disturbance or the risk of device failure (Applicant is again directed to Col. 8, lines 41-59 where it is disclosed that an alarm may be sounded to alert the patient that the CPAP apparatus has been placed in the standby mode, since the blower also will automatically enter the standby mode if the mask is knocked off or removed)."

It would have been obvious to further modify the CPAP respirator of Gruenke et al. to include a means for recognizing and analyzing a pattern of pressure and/or flow of breathable gas consistent with that of a leak or disconnection and subsequently shutting the ventilator down responsive thereto because it would have prevented wasting of breathable gas as taught by Froehlich et al. Further it would have been obvious to one having ordinary skill in the art at the time the device was made to further modify the

CPAP respirator of Gruenke et al to include an alarm signal indicative of the leak or disconnection so that the patient may be made aware that they must reconnect the dislodged mask and restart their CPAP therapy.

As to claim 2, Behbehani et al. teach an existing pressure level for breathing support is overlaid, at least temporarily, with a stimulating stream oscillating at a defined frequency (see steps #3 and #5 of flow chart illustrated in fig.1).

As to claim 3, Gruenke et al. as modified by Behbehani et al. (col.21, lines 38-45 of Gruenke et al.) teach a selection of the respective pressure amplitude (i.e. increase, decrease, maintain pressure as disclosed in col.21, lines 43-45 of Gruenke et al.) after a selective evaluation of an oscillatory pressure amplitude, occurring with a frequency of a stimulating stream in the air delivery of a patient (forced oscillation technique of respiratory impedance determination in Behbehani et al.).

As to claims 5 and 6, Gruenke et al. (fig.19) disclose at least one physical electrical signal is evaluated during the pattern recognition.

As to claim 7, Gruenke et al. (col.21, lines 8-10) disclose the calculated admittance to determine the "best fit" for a given treatment profile. In the process of arriving at the "best fit", a number of treatment profiles would be eliminated in favor of the "best fit". The treatment profiles that are eliminated are readable upon the recited class of errors in claim 7 because they are not found to be the proper treatment profile.

As to claim 8, Behbehani et al. teach an oscillating signal being evaluated using the forced oscillation technique of determining airway impedance (col.2, lines 10-20).

As to claim 9, Gruenke et al. disclose a static pressure signal (1806) being evaluated.

As to claim 10, Gruenke et al. disclose pressure variation being evaluated (col.21, lines 40-45), that is, the pressure of the CPAP air being delivered to a patient.

As to claim 11, Gruenke et al. disclose the flow signal (1802) being evaluated (col.20, lines 26-33 and fig.19).

As to claim 12, Gruenke et al. disclose a signal proportional to at least one of the flow signal (1802) and to a pressure-dependent signal (1806) is evaluated.

As to claim 13, Gruenke et al. disclose an electrical drive parameter of the compressed gas supply is evaluated (col.25, lines 50-62).

As to claims 14-16, Gruenke et al. (fig.19) illustrate distinctive form features of each of pressure, flow and admittance/impedance by their individual plots. The plotting of a flow data, pressure data and admittance/impedance data to their individual plots is exemplary of a class assignment being carried out.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amadeus S Lopez
Examiner
Art Unit 3771
February 2, 2007

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2/5/07